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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,434	03/15/2001	Glenn McGall	2719.2017-001	6484

33880 7590 10/29/2002

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EXAMINER

EPPS, JANET L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 10/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/810,434

Applicant(s)

MCGALL ET AL.

Examiner

Janet L Epps-Ford, Ph.D.

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 October 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 08 October 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 1-17

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☒ Other: see attached

Continuation of 3. Applicant's reply has overcome the following rejection(s): The rejection of claim 5 under 35 USC 112, first paragraph is withdrawn in response to Applicant's amendment.

### DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### *Claim Objections*

2. Claims 1-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Earhart et al. in view of McGall et al., for the reasons of record set forth in the Official Actions mailed 12-17-2001 and 7-03-2002.

Applicant's arguments filed 10-08-2002 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that Earhart et al. does not disclose or suggest varying of iodine concentration and specifically do not recite wherein the concentration of iodine used in the oxidation step ranges from about 0.005 M to about 0.05M, wherein the iodine concentration is about 0.02M. According to Applicants. The results (disclosed in the specification) are unexpected to one of skill in the art that varying concentration of iodine in the oxidation step would lead to significantly enhanced functional performance of arrays. Furthermore, Applicants argue that the claimed invention is not routine experimentation as asserted by the Examiner because a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.

However, contrary to Applicant's assertions, the variable that achieves a recognized result in the instant case is clearly disclosed in the prior art as iodine, wherein the recognized result is oxidation. The Earhart et al. reference clearly provides a method for specifically and

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uniformly synthesizing desired oligonucleotides within the elements (also called cells, or features) of a molecular array, wherein a phosphite triester group is oxidized by the addition of *iodine* in THF, pyridine, and water to form a phosphotriester group. (col. 7, lines 1-4). The instant invention requires the presence of iodine for the oxidation of a phosphite ester to a phosphate linkage, precisely the same result produced by the use of iodine in the teachings of Earhart et al. The presence of iodine in this oxidation reaction, as taught by Earhart et al., is the variable in the reaction that results in the oxidation process. Applicant's claimed concentration of iodine for use in oxidation, ranging from about 0.02M, or 0.005M to .05 M are a matter of optimization since the prior art discloses the general conditions for the oxidation of a phosphite ester linkage to a phosphate linkage. Moreover, the experiments, which yield unexpected results according to Applicants, involve the use of 0.02 M iodine as the oxidizing agent. It is unclear that the same results observed with 0.02M iodine will also be observed with concentrations of iodine from about 0.005 M to about 0.05 M iodine, wherein said results are necessarily unexpected in comparison to the use of concentrations of about .1 M iodine.

As stated in the prior action, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See MPEP § 2144.05(II). In the instant case the general conditions of oxidation, namely wherein the oxidation occurs in the presence of a solution comprising iodine in THF, pyridine, and water, are disclosed in the prior art. Therefore Applicant's recitation of a particular range of iodine concentration used in an oxidation solution is not considered inventive since there is no evidence that the particular concentration range recited in the instant claims is critical to the claimed method.

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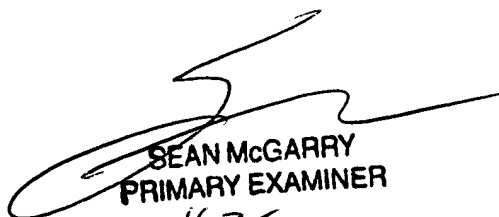
3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 9:00AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps-Ford, Ph.D.  
Examiner  
Art Unit 1635

*JLE*  
October 26, 2002

  
SEAN McGARRY  
PRIMARY EXAMINER  
1635